NIH eRA CGAP
Service Provider Q&A

July 21, 2004

1. The PDF format supports many components beyond support for color images. Potential features include:

- A Web link which, when clicked, takes you to a website (NIH generally does not generally support URLs except in some applications).
- IntraPDF links—this would be very useful for a revised application (e.g., "In response to the committees concerns we have revised Section 6.3.2"). Clicking on 6.3.2 would go to Section 6.3.2.
- Highlighting of text (e.g., changing background color, see Commenting/Note Tool).
- Attachment of Files, Sounds.
- Text boxes (Tools/Advanced/TextBox Tools).
- Drawing objects (Tools/Advanced Commenting/Drawing...).
- Comments and Stamps (Commenting/Note Tool, Stamp Tools).

Some of these elements may be created by accident as they may be used in the internal review process, others seem perfectly valid (e.g., drawing objects).

Q1. What happens if folks add any of these elements? Will any of them be purged in the image process? If so, which ones?

Answer:

We believe the following are technically possible, but would require testing to verify this and identify any limitations:

- **Link to a website.**
- **IntraPDF links.**
- **Highlighting of text.**
- **Drawing objects to an extent. There may be some limitations with drawing and colors.**
- **Comments and Stamps—If stamping means water colors, then yes.**

We need to do more research on text boxes and sounds to determine if these can be supported technically.

Q2. Assuming an element survives the image process, does that mean that NIH approves of such elements in an electronic submission?

Answer:

No. We will discuss these with the Center for Scientific Review and other NIH decision makers to identify which are acceptable.

Q3. If the answer to Q2 is no, then who is responsible to: a) inform PIs what is and is not acceptable, b) make sure PDFs do not include "improper" PDF elements.

Answer:

a) We will list what is acceptable and what is not in the Applicant Orientation package on the Partnership Page to assist Service Providers in conveying this information to applicants.

b) We have plans to create validations on PDF formats and will explore adding checks against improper PDF elements. Service Providers are encouraged to provide validations in their software to catch improper PDF elements.

2. Can we have another debriefing to hear how it is going for Service Providers and find if there are common problems?

Answer: Today's call included a debriefing.

3. Can you provide statistics about how many PIs participated in June/July, how long it took to get the grants finalized (on average) and how many folks dropped out and submitted by paper?

Answer:

- **34 PIs participated in June/July**
- **Statistics are not available regarding "how long it took to get the grants finalized."**
- **3 dropped out and submitted by paper**

4. At a recent NIH-sponsored conference, we spoke with companies interested in preparing NIH SBIR applications. Every single one was interested in electronic submission and supportive. It would be nice to be able to tell them when it is coming. Once we have a "1st pilot date," obtaining 100 pilot testers would be relatively easy. Each (no doubt) has technical savvy. Plus, making the process easier for SBIR would probably enhance the quality and quantity of applicants since confusion with the PHS 398 is a major stumbling block for SBIRs. After a pilot period, this is also a logical first group for whom application could be "mandatory" as the grumbling would be minimal.

1) Is there any chance for a Phase I SBIR Trial in December?

Answer: No.

2) If not, is adding an SBIR pilot on the horizon?

Answer:

We are planning to pilot SBIRs and STTRs in Summer 2005. The requirements for SBIR/STTR are very complex, and it will take a relatively long time for us to develop and implement these mechanisms.

5. On the assumption that one of our goals is to "load test" the entire eRA service...

A. Is there a number of proposals per service provider for the October round that NIH feels is desirable? If so are there figures for modular and non-modular?

Answer:

For modular simple grants, we will support as many as the Service Provider feels comfortable supporting. The Service Providers are expected to be mostly self sufficient for this type of application.

For full-budget, we will keep some limitation in numbers—about 10 per Service Provider.

B. Is there a maximum number of proposals per Service Provider for the October round (surely you don't want 1,000 proposals...)? If so are there figures for modular and non-modular?

Answer:

We will ask Service Providers for estimated numbers of submissions later this summer to enable NIH to plan for an increase in volume in the next pilot.

6. The current policy is that applicants should send in the appendix AFTER they have received an assignment to the SRA for that Study Section. This is different than the paper process with two implications:

1) They could potentially send in a more up-to-date appendix if they submit electronically.

a) Can we tell potential e-applicants that one benefit of e-submission is that that they will have extra days to prepare appendix materials and they can use that time to ensure the appendix has the most up-to-date information possible?

Answer:

That is fine. Applicants need to be sure that the appendix and application are in sync however (same numbering of figures, etc.).

b) If not, what do we tell them? Do we tell them that NIH requires them to prepare an appendix on the submit date and not change the contents or add to the contents?

Answer:

They should send in the appendix after they get the Study Section assignment.

2) They could potentially forget to send in the Appendix.

a) Can the SRA Assignment letter/email from Commons include a note that reminds electronic submitters to submit an appendix?

Answer:

We will consider this for the next release.

b) Is there a way CGAP could include the appendix preference? Thus there would be a mechanism so that the SRA would have some warning that a certain application should or should not have an appendix. This also would be a way the system could make folks aware that an appendix is not allowed (such as for SBIR Phase I).

Answer:

This can be considered for a future release when we will have electronically submitted appendices available. On the 398 Table of Contents page, applicants can indicate in the list of publications and other items that they are including an appendix.

7. Regarding the NIH new-person information update service:

1) In the schema, there is an “AddressModificationType” whose value may be “update,” “insert,” or “none.” Does this element work for “PhoneNumber,” “FaxNumber,” “Email” and other fields? Or does it only control the “PostalAddress”?

Answer:

The address modification type for both “update” and “insert” takes care of all the elements in the Postal Address and the Phone Number, Fax and Email elements. The other values, such as Position Title, degrees and name information, are always updated when there are any changes, whether the value of the address modification type is “none,” “insert,” or “update.” The values “insert” and “update” apply only to Address, which includes the postal address element and also the other elements such as Phone Number, Fax, and Email (the elements belonging to Contact Information tag in the schema.). For a better understanding, here a portion of the schema:

```
<xs:element name="ContactInformation" minOccurs="0">
      <xs:complexType>
            <xs:sequence>
                  <xs:element name="PostalAddress">
                        <xs:complexType>
                              <xs:sequence>
                                    <xs:element name="Street"
type="piupdatereq:nonemptytoken" minOccurs="0" maxOccurs="4"/>
                                    <xs:element name="City"
type="piupdatereq:nonemptytoken" minOccurs="0"/>
                                    <xs:element name="State"
type="piupdatereq:nonemptytoken" minOccurs="0"/>
                                    <xs:element name="PostalCode"
type="piupdatereq:nonemptytoken" minOccurs="0"/>
                                    <xs:element name="Country"
type="piupdatereq:nonemptytoken" minOccurs="0"/>
                              </xs:sequence>
                        </xs:complexType>
                  </xs:element>
                  <xs:element name="PhoneNumber" type="piupdatereq:nonemptytoken"
minOccurs="0"/>
                  <xs:element name="FaxNumber" type="piupdatereq:nonemptytoken"
minOccurs="0"/>
```

```
                    <xs:element name="Email" type="piupdatereq:emailtype"
minOccurs="0"/>
             </xs:sequence>
      </xs:complexType>
</xs:element>
```

2) After the update, does the user see the instant change via the person information request?

Answer:

Yes. The updates happen automatically.

8. How long will TEST be up? We want to do some demos to help overcome uncertainties and encourage greater participation at a research institution. Ideally we would go all the way through a submission with these folks, getting a PDF of the grant image back to show them. We would consider doing one or more of these demos later this month.

A recent message from the CGAP team stated "...TEST will be up for awhile longer..." I would hope that we could count on TEST being up essentially all of the time (except for brief, announced windows). What should we expect?

Answer:

We have requested an upgrade to the eRA environment in such a way that the SP will have a "permanent" test environment separate from the eRA internal test environments; and, it will, therefore, be more stable. We are planning to implement this over the summer, but we do not have a firm date at this time. In the meanwhile, we plan to leave the current test environment up and running until the next internal code release (which is scheduled for early August). In addition, we are exploring ways to integrate the Commons demo facility with the CGAP Service Provider testing environment to enable SPs to test and train in a more end-to-end fashion. We will keep you posted on the timeline for that as well.

9. Will the updates posted via this request be reflected immediately within the datastore (the actual NIH commons)? I assume that during the trial period (with test) the changes will be reflected only in the test Commons db, but that when this functionality goes to production, that successful update requests will be done automatically for the original data.

Answer:

The updates happen automatically.

It will behave the same way in production as in test once it is promoted to production. We have not yet established the date this service will be deployed in production because we have some policy issues to address first. We have not yet established the date this service will be deployed in production because we have some policy issues to address first. The eRA has the principle of single point of ownership (the person) for person information. Whatever the person provides, for example, in the Commons is what NIH will honor and what that person is responsible for. The login and password are used to assure accountability. We need to establish an accountability mechanism by which a Service Provider can update Person information before we can deploy this functionality in Production.

10. It looks from the schema as though there are two main 'modes' of update, i.e., 'update' and 'insert'. Is it possible to create (add) a new entry with either or both of these modes? That is, if I send an insert with a new Commons userid, will this add a new Commons entry? Is there a description somewhere of the semantics for 'update' and 'insert' that I could consult?

Answer:

The "insert" or "update" flag is only for "preferred employment address" and not for a new Commons account. The flag is named "AddressModificationType" to try to avoid any confusion about this. If "insert" or "update" is attempted on an account that does not exist, an error is thrown. In the future, we plan to develop a transaction to create a new entry, but have not yet determined when that will be. Again, we have some policy considerations to address.

11. What are the plans for the October pilot?

Answer:

The October/November pilot will be considered a "dress rehearsal" for production in January 2005. We will follow a similar schedule as with the other pilots. Please see question 5 for our plans on numbers of submissions.

12. Will there be any new application types or mechanisms accepted in the October pilot?

Answer:

We are planning to add the capability to handle applications in response to an RFA, as long they are one of our currently acceptable mechanisms.

13. We and our partners feel that the current method has at least two significant flaws relating to the composition of the Detailed Budget page. These concerns were sufficient to cause a partner to decide against submitting electronically.

A) How should the grant image display more than 7 or 8 personnel? One partner had 12 people on their project. Simply displaying them all at the top of the page is probably not the best way as it easily can lead to a single page being chopped into two or more pages which (1) do not resemble something submitted on paper and (2) would be unacceptable to NIH if they were submitted on paper.

Answer:

1) CSR has provided assurance to the grantee and review communities that NIH review staff are going to adjust to the differences in the appearance of the application. Please see the URLs: http://era.nih.gov/Projectmgmt/SBIR/CGAP/CSR_Assurance_Ltr_PI_05-28-04.pdf and http://era.nih.gov/Projectmgmt/SBIR/CGAP/CSR_Assurance_Ltr_SS_05-27-04.pdf. The expected outcome of the electronic process is not to make electronic submissions look exactly like paper but to ensure that electronic and paper applications alike are reviewed on the basis of their technical and scientific merits.

2) NIH review staff has told us, in response to this specific question, that they actually *prefer* to see the information for the extra people listed in the same place as the first seven or eight, with spillover onto an additional page if necessary for the data at the bottom of page 4.

B) The current schema and validation rules make it very challenging to preserve the detail currently requested and presented on paper, along with functionality already built into our program. Consider "Supplies". How do we expect users to prepare itemized data? The schema rightly permits them to

enter multiple descriptions, costs and totals. The validations restrict us to sending a single description text field and cost value that seem overly restrictive.

Answer:

The paper 398 does not explicitly support itemization of supplies, equipment, or other expenses. The paper provides space for one total, and a BLOCK for description. When an applicant itemizes via the paper submission, they structure it in the description block. There is simply not any place on page 4 where itemized descriptions and costs are captured in a tabular form and rolled up to provide the summary cost.

Since tabular itemization isn't there, the XML crosswalk prescribes that only a total summary cost and description be provided. Accepting tabular itemization in the crosswalk would *not* be an accurate modeling of the PHS 398 as it exists today.

The current XML model is the more flexible of the two options anyway. In certain ways, it is the tabular submission option that could be thought of as overly restrictive. Using the one-description block, SPs can provide whatever means they feel is appropriate for the applicant to author their budget, and can then format the itemized-description block that is to appear in the 398 before sending the generated XML "description" element to us. The description element can include not only the description/cost for each individual item but can include other text wherever desired to augment the itemization. Tabulating the information and leaving the rendering up to the central rendering process within the NIH exchange would remove much of that flexibility. The power to render these individual sections would effectively be taken away from the SPs, if tabular modeling were adopted.

Also, when the 424 Research and Related forms get OMB approval, they will not supply the ability to provide as much tabular itemization as we see now in the CGAP rendition of the schema. The Research & Related schema that everyone is looking at right now in CGAP was based on a very preliminary data model from a year and a half ago. The Research & Related approach has changed quite a bit in that time. When implemented later this year, the Research & Related is going to support tabular itemization for Equipment costs only. No other budget category is going to have an itemized section. Additional details for any budget category are going to follow the "attached description" model, which is consistent with the current CGAP ("one description block") approach.

We have raised these concerns to NIH stakeholders from Review, Grants Management, and Program. These representatives have indicated that this issue does not present a disadvantage for e-applicants; however, we will discuss this with them further.

One of the strategic goals for the CGAP program is to have end-to-end business process flows electronically. So the target state should be that the budget is fully fleshed out and validated in the incoming transaction, and can be automatically loaded into the software applications used by Grants Management and Program Managers at NIH. All changes made during Review and Award processes automatically re-calculate the budget and the notice of award is sent out with a consistent budget that the Service Provider can load into their own grants management system. Example: If the review specifies that a piece of equipment is not approved, the budget should recalculate automatically when that line item is removed.

All retyping of information from system to system, application to application should be avoided in the scenario.

While we are a long way from this scenario, there are components already in place at NIH that will facilitate it. However, the focus on the paper presentation could detract from the business to business implementation and overall benefits of the process.